

Food Good Manufacturing Practices

Title 21 Code of Federal Regulations (CFR) Part 110



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Food and Drug Branch

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Presentation Goals

Key Terms

Four Major Components

Questions

| | |
|--|---|
| Key Terms | <ul style="list-style-type: none"> • should – used to state recommended or advisory procedures |
| <ul style="list-style-type: none"> • adequate – what is needed to accomplish the intended purpose in keeping with good public health practice | <ul style="list-style-type: none"> • shall – used to state mandatory requirements |
| <ul style="list-style-type: none"> • suitable* – adapted to a use or purpose; proper; able; qualified <p><small>* Merriam-Webster.com</small></p> | |

GOOD MANUFACTURING PRACTICES

Sanitary Controls and Conditions

ADEQUATE

SUITABLE

Processing Controls

GMP Triple Threat

Food



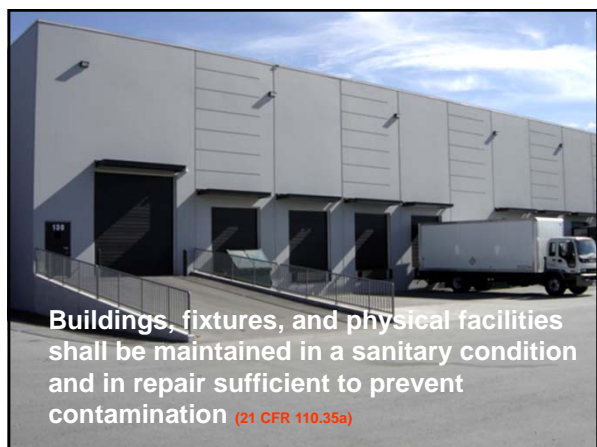
Food Contact Surfaces



Food Packaging and Materials









Grounds

The grounds under control of the operator must be maintained in a manner to protect against the contamination of food. (21 CFR 110.20 a1-4)

Storing equipment
Litter and waste
Weeds and grass
Roads and yards
Drainage
Waste systems

Grounds

The grounds not under control of the operator and not adequately maintained: care shall be exercised to prevent food contamination through (21 CFR 110.20a):

Inspection
Extermination
Other means



Facilities

Plant buildings and structures shall be suitable in size, construction and design to facilitate maintenance and sanitary operations. (21 CFR 110.20b5)

- Adequate lighting
- Safety fixtures



Facilities

Buildings and structures shall be of suitable size construction and design to facilitate maintenance and sanitary operations (21 CFR 110.20b1 and b2):

- Space for equipment and storage
- Food safety controls
- Operating practices
- Effective design
- Other effective means







**What do you
see?**



Bad News
- pest droppings

Good News
- visual inspection



**Your facility design
must allow for
product protection via
either:**



**Partition
Space
Time**



Facilities

Buildings and structures shall be of suitable size construction and design to facilitate maintenance and sanitary operations

(21 CFR 110.20b3,4):

Bulk Fermentation Vessels

Construction

- adequately cleaned
- adequate space
- good repair (21 CFR 110.35a)

Facilities

Buildings and structures shall be of suitable size construction and design to facilitate maintenance and sanitary operations

(21 CFR 110.20b4):

Construction

- drip and condensate



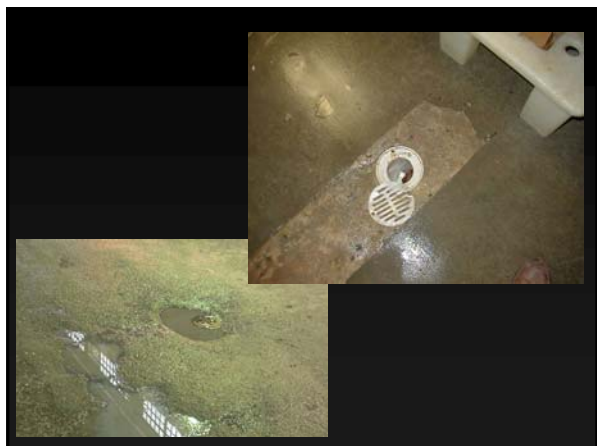




Sanitary Facilities (21 CFR 110.37 b, c, f)

Each plant shall be equipped with **adequate sanitary facilities**:

- Plumbing
 - Properly sized
 - Avoid constituting a source of contamination
 - Floor Drainage
 - No Back flow or Cross connections
- Sewage Disposal
- Rubbish and offal disposal







Water Supply

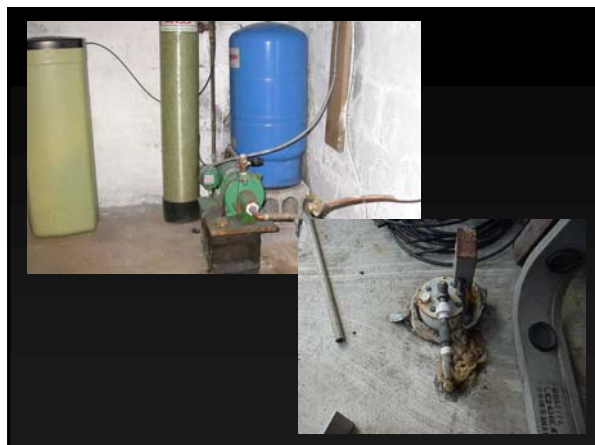


21 CFR 110.37a

- Adequate Source
- Safe and Sanitary Quality
- Suitable Temperature
- Appropriate Pressure

21 CFR 110.80a1

- Water used for washing, rinsing, or conveying food shall be of safe and sanitary quality.
- Water, if reused cannot increase the level of contamination in food.





Sanitary Facilities (21 CFR 110.37 d)

Toilet Facilities

- Readily Accessible
- Adequate
 - Sanitary Condition
 - Good repair
 - Self-closing doors
 - Properly located



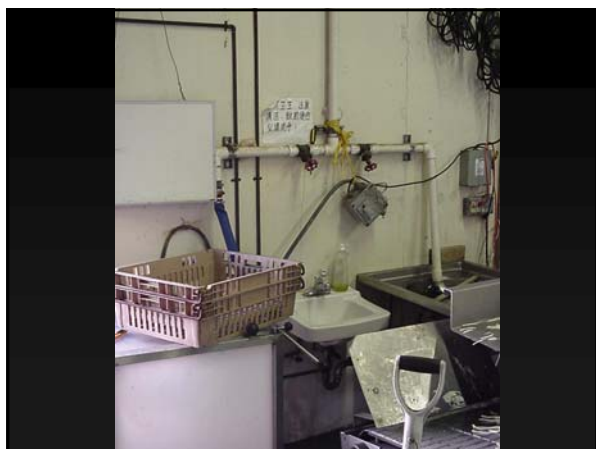




Sanitary Facilities (21 CFR 110.37 e)

Handwashing Facilities

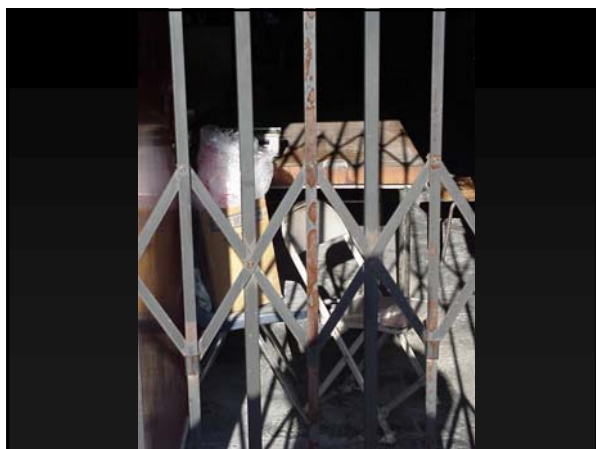
- Adequate (soap, towels)
- Hand sanitation facilities
- Convenient
- Running water
- Suitable temperature
- Fixtures designed not to re-contaminate
- Refuse receptacles
- Signage

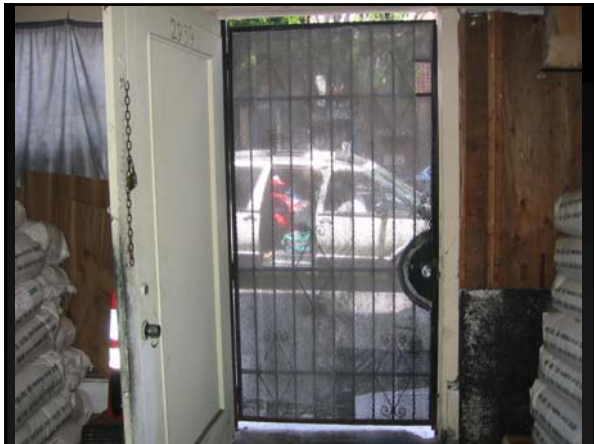




Pest Control (21 CFR 110.20b7)

Provide adequate screening or other protection against pests.





Pest Control (21 CFR 110.35c)

- No pests allowed in plant
- Effective measures taken to exclude from processing areas
- Use of insecticides, rodenticides under precautions and restrictions





Personnel (21 CFR 110.10a)

Plant management shall take reasonable measures to ensure:

- **Disease control**
 - Medical Exam
 - Observation
 - Exclusion
 - Reporting

Personnel (21 CFR 110.10b)

Plant management shall take reasonable measures to ensure:

- **Cleanliness through Hygienic practices**
 - Outer Garments
 - Personal Cleanliness
 - Washing hands thoroughly



Personnel (21 CFR 110.10b)

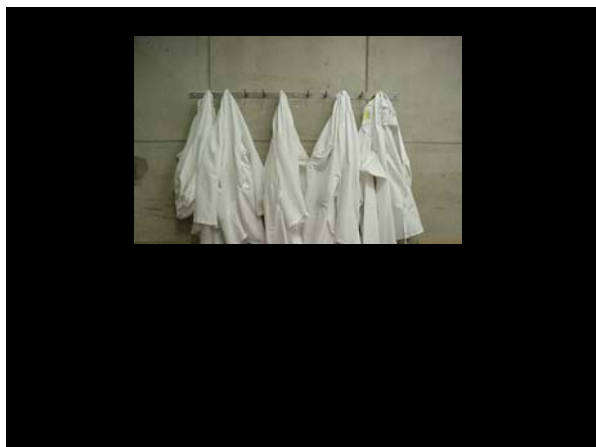
Plant management shall take reasonable measures to ensure:

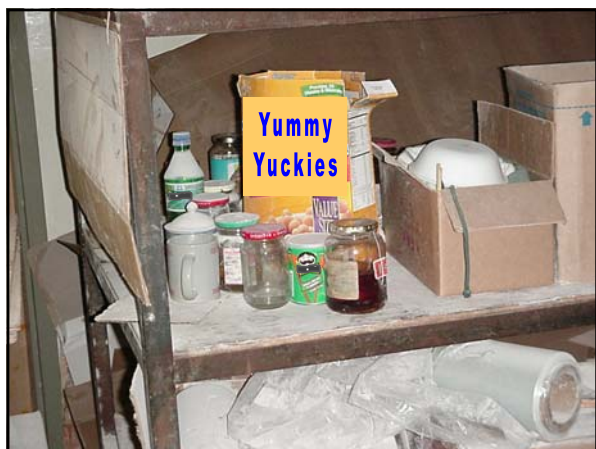
Cleanliness through Hygienic Practices

- Jewelry
- Gloves
- Hair restraints
- Storing clothing
- Areas of eating, drinking, smoking confined
- Foreign substances









Personnel

Plant management shall take reasonable measures to ensure:

Education and Training

(21 CFR 110.10c)

Proper Supervision

(21 CFR 110.10d and 110.80)





Equipment

Shall be designed and of such material, and workmanship to be **adequately cleaned** and shall be **properly maintained**.

(21 CFR 110.40a,d and 110.80b1)

- Preclude adulteration from:
 - lubricants
 - fuel
 - metal fragments
 - contaminated water
- Enables Maintenance



Equipment (21 CFR 110.40a,b)

- Designed to withstand food, cleaning and sanitizing
- Smoothly bonded seams
- Taken apart for thorough cleaning (21 CFR 110.80b1)







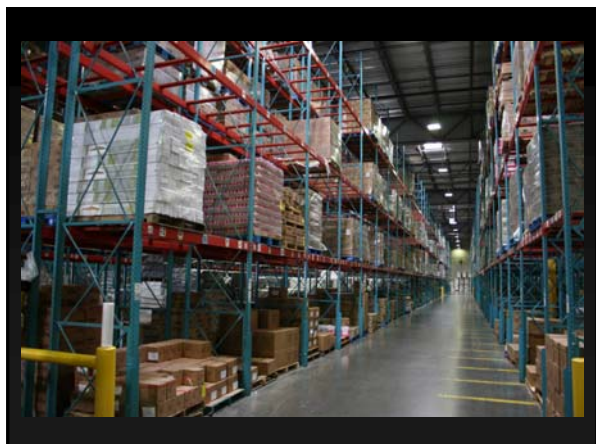
Equipment (21 CFR 110.40a)

- Installed and maintained to facilitate cleaning
- Corrosion resistant
- Non-toxic



Equipment (21 CFR 110.40c)

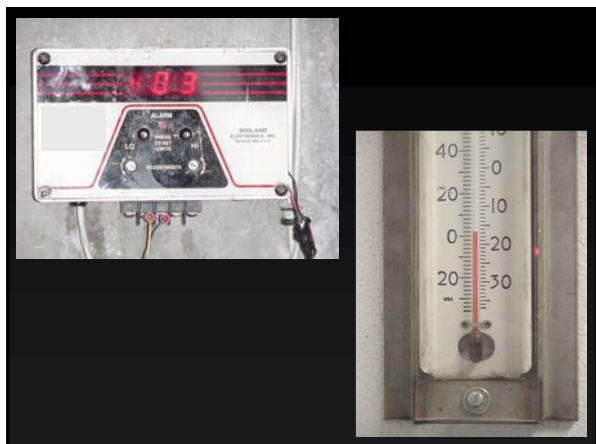
- **Non-food contact surfaces** constructed to be kept clean and cleaned as necessary to protect against contamination (21 CFR 110.35d3)





Equipment (21 CFR 110.40 e)

- **Temperature monitoring devices** required for freezers and cold storage units – accurate, automatic controls or alarm



Equipment (21 CFR 110.40 f and g)

- **Instruments** controlling or preventing the growth of microorganisms shall be:
 - accurate
 - maintained
 - appropriate in number
- **Compressed air** shall not be a source of contamination



Sanitary Controls (21 CFR 110.35a)

- Cleaning and sanitizing of **utensils** and **equipment** shall be conducted in a manner that protects against contamination





Sanitary Controls (21 CFR 110.35b)

- Cleaning and sanitizing **agents**
 - free from microorganisms
 - safe
 - adequate

Sanitary Controls (21 CFR 110.35 b)

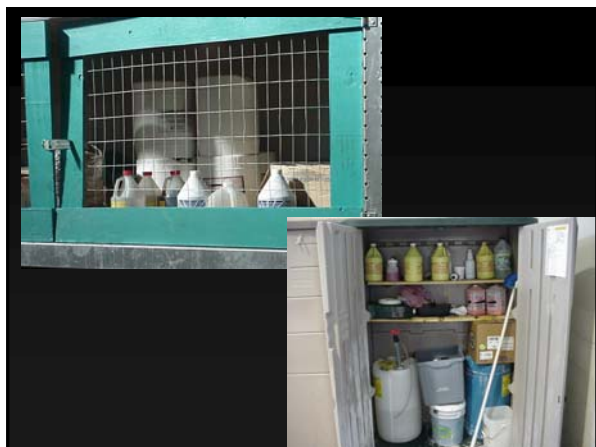
- Use:
 - as prescribed by law
 - protect against contamination
- Presence of Toxic agents
 - Cleaning and sanitizing
 - Laboratory
 - Maintenance and operations



Sanitary Controls (21 CFR 110.35b2)

- **Storage** of Toxic agents

- Properly Identified
- Held
- Properly stored



**Sanitation of
Food Contact Surfaces - FCS**
(21 CFR 110.35d)

Shall be cleaned as frequently
as necessary to protect from
contamination.

- FCS for Dry processing
- FCS for Wet processing

Sanitation of Food Contact Surfaces
(21 CFR 110.35d,e)

- Single service articles
- Sanitizing agents
- Portable equipment
(21 CFR 110.35e)

Equipment

Plant buildings and structures shall be
suitable in size, construction and design to
facilitate maintenance and sanitary
operations. (21 CFR 110.20b6)

- Adequate ventilation



Processes and Controls

(21 CFR 110.80)

All operations shall be conducted in accordance with adequate sanitation principles

Appropriate quality control operations shall be employed

All reasonable precautions shall be taken to protect from contamination

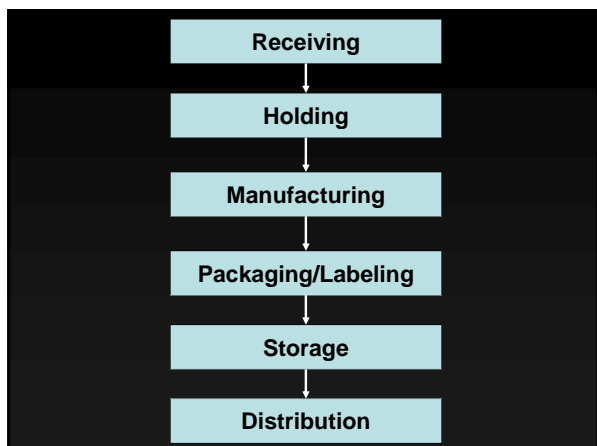
Processes and Controls

(21 CFR 110.80a2)

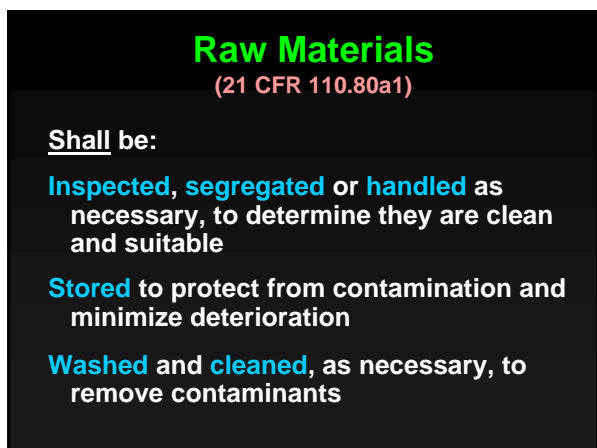
Ingredients **shall** not contain levels of microorganisms that may cause disease,

or

Ingredients **shall** be pasteurized or otherwise treated







Acceptable food storage practice?



Raw Materials

(21 CFR 110.80a1)

Containers should be inspected to ensure they do not contribute to contamination or deterioration


Raw Materials


(21 CFR 110.80a3)

Susceptible to **aflatoxin** or other **natural toxins** shall comply with FDA regulations, guidelines, and action levels.

Susceptible to pests or other undesirable microorganisms or extraneous materials shall comply with FDA defect action levels.

Address <http://www.fda.gov/food/guidancecomplanceregulatoryinformation/guidancedocuments/sanitation/ucm156714.htm>

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Defect Levels Handbook

The Food Defect Action Levels

Levels of natural or unavoidable defects in foods that present no health hazards for humans

1. Introduction
2. Products without defects
3. Use of Chemical Substances to Eliminate Defect Levels
4. Using This Food Defect Action Level Booklet
5. Additional Copies
6. Glossary
7. Commodities and Defect Action Levels
 - A-C
 - D-H
 - O-P
 - R-Z

Raw Materials

(110.80a5,7)

- Held in **bulk containers** shall be held to protect from contamination.
- Materials scheduled for **re-work** shall be identified as such.

Raw Materials

(21 CFR 110.80a6)

Frozen ingredients shall be held frozen. If thawed, it shall be done in a manner that prevents adulteration.

Manufacturing Operations

(21 CFR 110.80b2)

Compliance through **monitoring** of:

Physical Factors

Time

Flow Rate

Aw

pH

Temperature

Pressure

Humidity

Manufacturing Operations
(21 CFR 110.80b2)

All food manufacturing, including packaging and storage shall be conducted under conditions and controls to minimize the potential for the **growth of microorganisms and contamination.**

Manufacturing Operations
(21 CFR 110.80b3)

FOODS THAT CAN SUPPORT THE RAPID GROWTH OF MICRO-ORGANISMS OF PUBLIC HEALTH SIGNIFICANCE SHALL BE HELD AND PROCESSED IN A MANNER THAT PREVENTS THE FOOD FROM BECOMING ADULTERATED





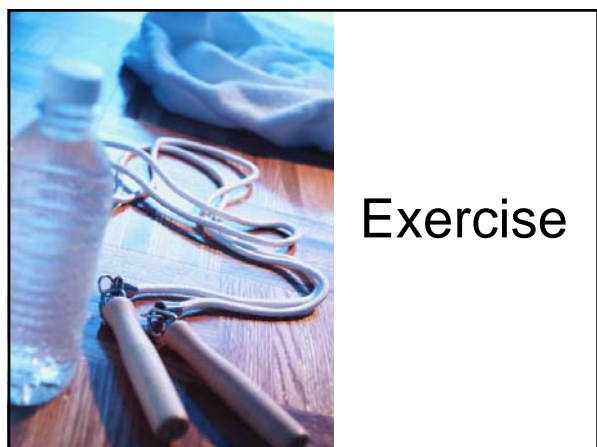
Manufacturing Operations (21 CFR 110.80b3)

- Refrigerated foods at $\leq 45^{\circ}\text{F}$
- Frozen foods in frozen state
- Hot foods at $\geq 140^{\circ}\text{F}$
- Heat treating or acidifying foods held at ambient temperatures in hermetically sealed containers

Manufacturing Operations Food Safety Systems

- HACCP (110.80 b,12,i)
- ISO





Additional Process Controls

| | |
|-------------------------|---------------------------|
| • Recall Program | • RFR |
| • Complaint Program | • Validation of Processes |
| • Monitoring | • Audit Program |
| • Environmental Testing | • Bioterrorism |
| • Product Analysis | |

If You Have Questions Contact:

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